

IN RE: DIET DRUGS (PHENTERMINE/  
FENFLURAMINE/DEXFENFLURAMINE)  
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

V.

AMERICAN HOME PRODUCTS  
CORPORATION

2:16 MD 1203

9096

June 25, 2013

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Wayne Matlock, Ms. Matlock's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In November, 2008, claimant submitted a completed supplemental Green Form to the Trust signed by her attesting physician, Wassim H. Shaheen, M.D. Based on a February 28, 2008 echocardiogram,<sup>4</sup> Dr. Shaheen attested in Part II of Ms. Matlock's Green Form that she suffered from moderate aortic regurgitation and had surgery to repair or replace the aortic and/or mitral

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3. (...continued)  
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Because claimant's February 28, 2008 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated April 24, 2002 to establish her eligibility to receive Matrix Benefits.

valve(s) following the use of Pondimin<sup>®</sup> and/or Redux<sup>™</sup>.<sup>5</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$645,047.<sup>6</sup>

Dr. Shaheen also attested that claimant suffered from aortic stenosis. Under the Settlement Agreement, the presence of aortic stenosis, which is defined as "[a]ortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation," requires the payment of reduced Matrix Benefits. Settlement Agreement § IV.B.2.d.(2)(c)i)e). In addition, Dr. Shaheen attested that claimant did not have aortic sclerosis at the time she was first diagnosed with mild or greater aortic regurgitation. Under the Settlement Agreement, the presence of aortic sclerosis in claimants who were sixty (60) years of age or older at the time they were first diagnosed as FDA Positive<sup>7</sup> also requires the payment of reduced Matrix Benefits. As the Trust does not contest Ms. Matlock's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

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5. In addition, Dr. Shaheen attested that claimant suffered from mild mitral regurgitation, an abnormal left atrial dimension, and New York Heart Association Functional Class II Symptoms. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin<sup>®</sup> and/or Redux<sup>™</sup>." See Settlement Agreement § IV.B.2.c.(3)(a).

7. FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve." Settlement Agreement § I.22.a.

In April, 2009, the Trust forwarded the claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala concluded that there was a reasonable medical basis for the attesting physician's finding that claimant had aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation based on claimant's February 28, 2008 echocardiogram. Dr. Penkala also determined that there was no reasonable medical basis for Dr. Shaheen's representation that Ms. Matlock did not have aortic sclerosis at the time she was first diagnosed with mild or greater aortic regurgitation, which occurred when she was sixty (60) years of age or older. Dr. Penkala explained, in pertinent part, that:

To me the 2D appearance of the [aortic valve] on the [echocardiogram] study [of] 4/24/02 is consistent [with] [aortic valve] sclerosis (mild leaflet thickening + calcification) without stenosis. Although the peak velocity across the [aortic valve] (and the x/peak gradients) are slightly higher than usually seen [with] [aortic valve] sclerosis this most likely is due to the [increased] flow across the aortic valve due to moderate [aortic insufficiency]. The claimant was 60 years old at the time of this [echocardiogram] study.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination that Ms. Matlock was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>8</sup> In

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8. Claims placed into audit on or before December 1, 2002 are  
(continued...)

contest, claimant argued that her claim only can be reduced if "the sclerosis or calcification ... appeared at the time the diagnosis of valvulopathy was first made[,] April 24, 2002." Thus, according to claimant, she should receive Matrix A-1 benefits because the auditing cardiologist did not find the presence of aortic stenosis based on claimant's April 24, 2002 echocardiogram and the physician that reviewed her prior claim under the Seventh Amendment did not find the presence of either aortic sclerosis or aortic stenosis based on claimant's April 24, 2002 echocardiogram.

The Trust then issued a final post-audit determination, again determining that Ms. Matlock was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Matlock's claim should be paid. On December 15, 2009, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8362 (Dec. 15, 2009).

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8. (...continued)  
governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Matlock's claim.

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 24, 2010. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for finding that Ms. Matlock did not have aortic sclerosis at the time she was first diagnosed with mild or greater aortic regurgitation and aortic stenosis with an aortic valve area  $< 1.0$  square centimeter by the Continuity Equation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for these findings, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for these findings, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, claimant reasserts the arguments that she made during contest. In addition, claimant argues that the auditing cardiologist's determination is "a different diagnosis based on speculation" because she only stated, "although the peak velocity across the [aortic valve] and the x/peak gradients are slightly higher than usually seen with

[aortic valve] sclerosis this most likely is due to increased flow across the aortic valve due to moderate [aortic insufficiency]."

In response, the Trust argues that Ms. Matlock failed to demonstrate a reasonable medical basis for finding that her April 24, 2002 echocardiogram did not demonstrate aortic sclerosis because the Seventh Amendment reviewer did not review her April 24, 2002 echocardiogram for this condition. In addition, the Trust contends that claimant's request for "a temporal coincidence of FDA positive diagnosis and diagnosis of aortic sclerosis and/or aortic stenosis" as a prerequisite to application of these specific reduction factors is not supported by the relevant language of the Settlement Agreement.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, claimant does not adequately challenge the findings of the auditing cardiologist with respect to the existence of aortic sclerosis or aortic stenosis. Claimant does not challenge at all the existence of aortic stenosis on her February 28, 2008 echocardiogram,<sup>9</sup> and her only challenge to the presence of aortic sclerosis is that such finding is inconsistent with the results of her Seventh Amendment review. Contrary to claimant's assertion, however, the Seventh Amendment reviewer did not

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9. The report of claimant's February 28, 2008 echocardiogram states, "There is at least moderate aortic stenosis with a mean gradient of 34 mm. The calculated valve area is 0.9 cm<sup>2</sup>."

determine that Ms. Matlock's April 24, 2002 echocardiogram did not demonstrate aortic sclerosis. In fact, the report of that review specifically states, with respect to aortic stenosis, aortic sclerosis, and other specific medical conditions:

No values are reported for these measurements because the Participating Physician who read this Relevant Echocardiogram found that the Aortic Valve did not meet the minimum Degree of Regurgitation threshold required by the terms of the Seventh Amendment for the Claim to be one that could qualify for benefits Subject to Medical Review.

Mere disagreement with the auditing cardiologist without identifying any specific error by her is insufficient to meet a claimant's burden of proof.

We also disagree with Ms. Matlock that the reduction factor of aortic stenosis only applies when it is diagnosed at the time the requisite level of valvular regurgitation is found to exist. Although the parties considered temporal limitations in connection with certain reduction factors, nothing in the Settlement Agreement provides for a temporal limitation for the reduction factor of aortic stenosis. Compare Settlement Agreement § IV.B.2.d.(2)(c)i)e) ("Aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation") with Settlement Agreement § IV.B.2.d.(2)(c)iii)b) ("Bacterial endocarditis prior to Pondimin® and/or Redux™ use"); see also Mem. in Supp. of PTO No. 8822, at 9-11 (Feb. 22, 2012), aff'd,



No. 12-3138, 2013 WL 2166119, at \*2-3 (May 21, 2013).<sup>10</sup> We must apply the Settlement Agreement as written. As claimant does not contest that she has aortic stenosis as defined by the Settlement Agreement, the Settlement Agreement mandates that her claim be reduced to Matrix B-1.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have aortic sclerosis and aortic stenosis. Therefore, we will affirm the Trust's denial of Ms. Matlock's claim for Matrix A, Level III benefits and the derivative claim submitted by her spouse.

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10. Although the reduction factor of aortic sclerosis only applies if claimant is sixty (60) years of age or older at the time he or she is first diagnosed as FDA Positive, see Settlement Agreement § IV.B.2.d.(2)(c)i)c), claimant does not contest this application.